SUMMARY MINUTES

OF THE

GENERAL HOSPITAL AND PERSONAL USE DEVICES

ADVISORY PANEL MEETING

OPEN SESSION

August 2, 1999

Room 020
9200 Corporate Blvd.
Rockville, MD

General Hospital and Personal Use Devices Advisory Panel Members
August 2, 1999

Charles Edmiston, Ph.D.
Chair

Martha T. O'Lone
Executive Secretary

Joseph F. Fowler, Jr., M.D.
Voting Member

William A. Rutala, Ph.D.
Voting Member

Marcia Ryder, MSN
Voting Member

Margaret Avila-Monge, RN/NP, M.S., M.S.N.
Voting Member

Robert Dacey
Consumer Representative

Salvadore Palomares
Industry Representative

FDA Participants

Timothy A. Ulatowski
Director, Division of Dental, Infection Control and General Hospital Devices
ODE/CDRH/FDA

Lireka P. Joseph, Dr.PH, Captain, USPHS
Director of Office of Health and Industry Programs
CDRH/FDA

Von Nakayama, Captain, USPHS
General Hospital Devices Branch
ODE/CDRH/FDA

Chiu S. Lin, M.D.
Chief, Infection Control Devices Branch
ODE/CDRH/FDA

Patricia Cricenti
Chief, General Hospital Devices Branch
ODE/CDRH/FDA

Irene Naveau, R.N.
General Hospital Devices Branch
ODE/CDRH/FDA

Anne Farrell, M.D.
CDER

Donna Chandler, M.D.
CBER

Larry Kessler
FDA

Charles Ho, M.D.
FDA

OPEN SESSION—August 2, 1999

Martha T. O'Lone called the Open Session to order at 8:40 a.m. by reading the conflict of interest statement and noting that full waivers had been granted to Dr. Rutala and Ms. Ryder. She read appointments to temporary voting status and acting panel chair for Dr. Charles Edmiston and asked the other panel members to introduce themselves.

FDA Presentation on Postmarket Surveillance

Larry Kessler discussed postmarket surveillance and methods of postmarket evaluation at CDRH. He explained that medical devices have a definable life cycle, in which the clinical community plays an important role in providing feedback during postmarket evaluation. He outlined the questions assessed in the postmarket period and described the Medical Device Reporting (MDR) Program, which provides limited but critical information to FDA about devices with problems, and he listed the possible actions prompted by such a report. Mr. Kessler discussed the two postmarket authorities, postmarketing surveillance and postapproval authority, and outlined the criteria for a panel to suggest postmarketing surveillance as well as study designs used in postmarketing surveillance. He acknowledged the frustrations involved in monitoring postmarketing and challenged the panel to ensure that a postmarketing study will be of primary importance, to specify the public health question it is to address, and to note what will be done with the data collected. He briefly outlined the future for the MDR and Postmarketing Surveillance programs.

FDA Presentation on Y2K Information

Dr. Charles Ho of the FDA gave the panel an update on the Year 2000 date problem and computerized medical devices. Dr. Ho defined the types of medical devices that are subject

to Year 2000 problems. He asked the panel to provide advice regarding problematic devices, identify types of devices that could present risks to patients because of date problems, and suggest actions to reduce risks from Year 2000 problems.

Dr. Ho summarized FDA/CDRH activities on the Year 2000 problem to date. He noted that the FDA has a biomedical equipment database on its World Wide Web site that is continually updated and contains voluntary submission of data provided by manufacturers. The database shows that many companies have not yet reported. Most of the noncompliant products have date stamping problems, which is a less serious issue, but a limited number have operational problems. Manufacturers are providing a variety of solutions. The FDA can require recall of devices presenting a significant risk to public health and will monitor reports of Y2K problems with emphasis on devices that could present significant patient risks. Dr. Ho listed future CDRH/FDA activities and healthcare facility issues and asked the panel to give the problem serious consideration.

Panel Chair Dr. Edmiston noted that the panel had a twofold charge for the day: to discuss guidance for needle-less or protected sharps systems and to discuss jet injector systems.

GUIDANCE DEVELOPMENT FOR PROTECTED SHARPS SYSTEMS

FDA Presentation

Tim Ulatowski, director of the Division of Dental, Infection Control, and General Hospital Devices, gave an overview of the protected sharps issue, noting that panel input was sought on a guidance document, which would then be revised and posted for further

comment. He noted that the discussion would primarily involve protected syringe devices, and he was particularly interested in the clinical survey section of the document.

Irene Naveau presented the Sharps Injury Guidance Document, a supplementary guidance for manufacturers seeking 510 (k) approval. She reviewed the regulatory background of the guidance, which was written in March 1995. Ms. Naveau defined medical devices with sharps injury prevention features and needle-less systems and outlined various lists of desirable performance characteristics for these systems as defined and surveyed by other organizations. She listed the elements of the guidance document, including device description, labeling specification, and performance testing, which includes recommended tests.. Ms. Naveau noted that a reanalysis of the FDA document is needed for consistency and additional information, and she read the FDA questions to the panel.

Lireka P. Joseph, director of the Office of Health and Injury Prevention at FDA, described the outreach and educational activities in this area in the context of the FDA and OSHA (Occupational Safety and Health Administration) mandates. FDA's role has included clearance of devices with sharps injury prevention features, cosponsoring of meetings with other organizations, and issuance of safety alerts and guidance documents on injury prevention. Ms. Joseph asked for panel assistance in recommending a mechanism to increase user awareness of safe use and in assessing need for educational programs to encourage safe and effective use.

Presentations by Users of Protected Sharps Systems

Dr. June Fisher of the Trauma Foundation and San Francisco General Hospital discussed a training program for the development of innovative technology, the TDICT. This

project is a joint effort of health care workers, industry product designers, and industrial hygienists, which has produced a list of criteria for device evaluation and selection. Dr. Fisher described scenarios or simulations for evaluation of medical devices and stated that users should be involved from the beginning of the design process. She listed five recommendations for the FDA to purse in prevention of worker exposure to sharps injury, including labeling of all sharps devices on whether safety features are present, active solicitation of failure and inadequacy data, promotion of criteria for pilot testing, active collection of failure data from such testing, and expanded requirements for simulation testing.

Toni Hughes, RN, BSN, CNOR, spoke on behalf of the **Association of Operating Room Nurses, Inc. (AORN),** stating that AORN supports the development and use of products such as safe needle devices, to prevent unnecessary exposures of perioperative personnel to hazardous bloodborne infections. She gave statistics on sharps injuries and supported the FDA's role in contributing to the development and manufacture of high-quality, safe, affordable, and effective devices.

Mary Alexander spoke on behalf of the **Intravenous Nurses Society (INS),** saying that INS supports engineering and work practice controls that eliminate or minimize exposure of the healthcare worker to bloodborne pathogens She listed blood collection device design characteristics that result in an effective safety device and said that requiring all health care facilities to use needleless systems and protected sharps, along with training and education on the use of safer devices, would help prevent needlestick injuries. She reported that INS contends that the best way to reduce the risk of accidental neddlesticks is through ongoing

education, training, and competency testing, use of vascular access devices that minimize risk of such injuries, and compliance with OSHA's bloodborne pathogen standards.

Susan Wilburn of the American Nurses Association (ANA) discussed recent needlestick injuries and presented statistics on the estimated percentage of the U.S. market using safety devices. She discussed hazards to healthcare workers and risks of bloodborne disease, as well as the efficacy of phlebotomy safety devices in reducing injuries. She recommended removing the barriers to implementation of such devices through user training in use testing and evaluation.

OPEN PUBLIC HEARING

Panel Executive Secretary Martha O'Lone read two statements into the record. The first, a letter from **Dr. James Cone and Martha Davis of the Occupational Health Branch of the California Department of Health Services**, asked the FDA to establish a process to standardize product safety claims across all states with legislation similar to that enacted in California. They recommended provision of a way to search the Releasable 510 (k) database for engineered safety products or to consider new product codes specifically to identify needle devices with engineered safety components. They recommended that the guidance document incorporate specific safety criteria on what constitutes a safe sharps disposal container and that the FDA prescribe specific test methods to assess safety performance of a needle safety device or other medical device that claims to be safer than a standard device.

Ms. O'Lone also read a letter from **BioMedical Disposal** recommending that the guidance document be revised to reflect changes in technology, regulations, and the marketplace since March 1995 and stating specifically that the guidance should be revised for 510 (k)s for

devices with built-in sharps destruction. Ms. O'Lone stated that the specific changes listed in the letter would be noted in written revisions.

Lori Goodenough spoke on behalf of the **Service Employees International Union (SEIU).** She discussed SEIU's efforts since 1986 on behalf of a bloodborne pathogens standards and on behalf of better regulation of sharps. She listed 12 critical elements necessary to achieve success at the worksite level during the conversion from conventional to safer needles and other sharps. These included mandatory training, review of manufacturers' written and video educational materials, required clinical experience for manufacturers' representatives, performance testing on new devices with three return demonstrations, retraining for workers who fail device testing, follow-up testing for 30 days, educational efforts on device and exposure risks and reporting methods, and ongoing monitoring or surveillance data on injuries.

Kathryn Duseman of Retractable Technologies, Incorporated recommended that all devices should undergo the same rigorous testing and evaluation. She stated that criteria are needed for length of exposure, both in and out of the patient. Device safety after assembly and when disassembled is also critical, as are design issues.

Panel Discussion and Recommendations

The majority of the panel agreed that actual demonstration of clinical efficacy should be required for any claim, suggestion, or hint that a product will reduce sharps injury. If there is no claim of injury reduction, an actual clinical trial may not be needed. The Industry Representative disagreed, but the consensus was that clinical use studies should be required for any specific claim regarding sharps injury protection features.

On minimum criteria for actual clinical use studies, the panel recommended six provisions. 1) Body sites to be tested should conform to the expected use of the device. 2) Sample size should be based on a clinically meaningful reduction of needlestick injuries for devices claiming injury reduction, although a reasonable number for sample size is an issue for FDA-industry collaboration. 3) All devices should be tested on appropriate tissues, and data showing efficacy should be properly studied by a masked, independent investigator. 4) Appropriate populations should be studied. 5) The device studied should be the actual device, not a prototype. 6) Multiple sites, at least two or more, should be used to increase user variability. The panel recommended that FDA make efforts to investigate the optimal way to study devices in a home care environment with comments from industry, but they did not propose it as a mandate.

On evaluation methods, the panel recommended that information from the TDICT, SEIU, and New York State Department of Health projects be included in addition to the surveys already in use. The panel thought the evaluation criteria listed in the guidance document appropriate but recommended that the FDA look at developing standard testing protocols, specifically regarding microbial challenge testing. Labeling criteria should include thorough documentation of intended use on the packaging insert. Educational tapes or other strategies are inherently valuable and should be made more available to the user through in-services.

As noted, standard testing protocols for microbial contamination should be considered for premarket review. On user education, the panel recommended that any requirement should be broad-based, with the specifics of training and education left up to the manufacturer, with FDA approval. It was suggested that manufacturers look at the private sector to see how it

influences consumer education through vehicles such as tapes, posters, and other multi-media documentation. Again, the importance of the home health care area was stressed.

The panel noted a clear need for a mechanism for post-market surveillance, although 100 percent compliance is unlikely. It was noted that the EPINET database complements the CDC database and provides an absolute benchmark for such studies.

GUIDANCE DEVELOPMENT FOR JET INECTORS

Tim Ulatowski gave an overview of the jet injector, a drug and biologic delivery device. He noted that there are significant safety concerns and a potential need to cover new technologies in the guidance document.

Captain Von Nakayama of the General Hospital Device Branch gave an overview of jet injectors, also known as needle-free injections, in which he noted that they are preamendment devices providing an alternative means of administering specific or general drugs or biologics for individual or multiple patient use. He described the device as a nonelectrically powered fluid injector used by a health care provide to give hypodermic injections by means of a high velocity jet of fluid that penetrates the skin surface. Captain Nakayama discussed regulatory controls for class II devices and noted that jet injectors fall into two categories of intended use: personal and multiple-patient. He outlined the various dosage forms, different administration sites, and action mechanisms. Review issues and concerns include identification of appropriate legally marketed comparison devices and three distinct reviews--physical and mechanical properties, performance characteristics, and combination products. He compared jet injectors with needle and syringe injections. Captain Nakayama listed three questions for panel discussion and defined valid scientific evidence.

Bruce Weninger of the Centers for Disease Control (CDC) discussed needle-free injection as a solution to the problem of excessive injections or multiple vaccination injections during pediatric visits. He gave examples of needle-free injection systems developed for diabetics and of injectors for immunizations, both reusable and single-use. He noted that prefilled vaccine cartridges would be an advance in vaccine technology and that high-speed, high-workload devices would provide mass immunization devices for epidemics. Dr. Weninger discussed clinical aspects of jet injectors, listing medicaments they deliver. He stated that the immunogenicity of jet-injected vaccines was generally equivalent to or better than needle/syringe injections but showed different patterns of deposition. Controlled clinical studies have found somewhat higher rates of local adverse events, with pain generally less than or similar to needle-syringe injections. He discussed tissue deposition by jet injectors, listing determinants of deposition site and noting that deposition may not be a significant issue.

On safety, Dr. Weninger discussed one outbreak of hepatitis B associated with jet injections in a weight reduction clinic. He noted use of a bovine model to evaluate jet injector safety and results of acetone swabbing in a laboratory study on contamination of jet injector devices. Various organizations such as the World Health Organization (WHO), the CDC, and the U.S. Department of Defense have policies on multiple-use nozzle jet injectors, which he outlined. Regulatory issues for jet injectors include needle-free injectors as empty drug delivery devices, prefilled vaccines used with injectors as primary drug packaging, and safety evaluation of injectors with reusable fluid pathways or nozzles.

Presentations by Users

There were no requests to present to the panel

Presentations by Industry

Glen Austin of the Program for Appropriate Technology in Health (PATH) discussed needle-free injection fundamentals, including standardization and regulatory issues, variations among devices, and needle-free functional safety testing. He discussed the rationale behind needle-free injectors and discussed how jet stream quality and dispersion variables can be measured. He listed physical characteristics such as drug compartment, driving mechanism, nozzle design, and trigger mechanism, based on research by an ad hoc discussion group that evolved from the ISO Standards group. Safety aspects are mostly concerned with dose accuracy, freedom from cross contamination, short dosage, or accidental firing. Quality aspects include dose accuracy and durability. Mr. Austin discussed fluid-path elements and user-interface issues, as well as disposal and reuse standards and filling and dosage issues. He suggested baseline tests on targets, force, and penetration results.

Robert Harrington from the Association of Needle-Free Injection Manufacturers (ANFIM) discussed the objectives of ANFIM and declared its message was that the children of the world need needle-free injection products and the world needs needle-free injection products. He stated that the "developed" world cannot continue to pollute, contaminate, and infect the "developing" nations of the world by a policy which recommends disposable needles when they are routinely reused dirty or improperly disposed of. He asked whether needle-free products really require new regulations, noting that there has only been one documented case of contamination out of hundreds of millions of jet injections.

Mr. Harrington also spoke on behalf of **American Jet Injector, Inc.,** discussing the history of the Ped-o-Jet high-workload injector, which was used by the U.S. military since

1965 without a case of reported contamination. He summarized the history of the hepatitis B outbreak associated with a Med-E-Jet device and the subsequent development of the WHO policy against jet injector devices. He also listed other testing on jet injectors by WHO, CDC, and PATH, stating that the premise that high workload jet injectors are unsafe and easily contaminated has yet to be proven. Mr. Harrington listed eight reasons to use high workload jet injectors in pandemics, national immunization programs, and chemical and biological response teams. He mentioned several possibilities for the future for these jet injectors. Mr. Harrington discussed the risk of disease transmission with jet injection and what an acceptable level of risk would be in cases of epidemics or chemical/biological attacks.

OPEN PUBLIC HEARING

Dr. Fisher of the Trauma Foundation raised the issue of possible effects of jet injectors on health care workers in terms of muscular-skeletal or aerosol aftereffects.

Ms. Duseman of Retractable Technologies, Inc., noted that many of the new technologies that are nonreusable are safe for health care workers and patients. She suggested that issues affecting health care workers with jet injectors are not yet known and questioned the concept of an acceptable level of risk.

Mr. Harrington of American Jet Injector, Inc., stated that the concept of acceptable risk levels was not his own but one used in assessing public health risks.

Bud Anthony of the Biologics Consulting Group asked whether it is possible to determine if multiple vaccines commingle. **Mr. Austin of PATH** stated that such studies have not been done but can be.

In reply to a panel question, **Dr. Weninger of the CDC** stated that it is possible to develop jet injection to minimize risks of contamination, but the challenge lies in developing a methodology to evaluate such risk. He thought it more promising to develop a disposable cartridge in a multiple-use gun.

Larry Salerno of Retractable Technologies stated that small business on limited budgets need regulatory assistance rather than more regulation.

FDA Questions and Panel Summary Recommendations

In discussing key issues to be considered in the premarket evaluation of jet injectors and what data would be appropriate on them, the panel recommended that for devices that have a predicate, the FDA can determine whether additional testing would be indicated. For new technologies, the FDA should require bench engineering-type data and additional documentation on effective therapeutic dose delivery and accuracy to determine safety.

The panel's second recommendation was that the FDA should look at potential review methodologies to determine the potential for cross-contamination with these devices. It also recommended a postmarket surveillance program to track these devices once they are out on the market and once they leave the hands of health care professionals.

Panel Chair Dr. Edmiston thanked the panel and all participants in the session and adjourned the session at 4:10 p.m.

I certify that I attended the Open Session of the General Hospital and Personal Use Devices Panel Meeting on August 2, 1999, and that this summary accurately reflects what transpired.

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Martha T. O'Lone
Panel Executive Secretary

I approve the minutes of this meeting as recorded in this summary.

Charles Edmiston, Ph.D.
Acting Panel Chair

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